

*placed by
Article 19 Amend't.*

Rec'd PGT/PTO 10 JUN 2005

10

10/538277

CLAIMS

5 Having described the invention, it is considered an innovation and therefore the contents of the following clauses are claimed as property:

- 10 1. Pharmaceutical composition characterized by containing Silymarin and Carbopol and a pharmaceutically acceptable vehicle.
2. Composition in accordance with claim 1 characterized by containing 3 to 7% Silymarin and 0.2 to 0.6% Carbopol.
- 15 3. Composition in accordance with claim 2 where it preferably contains 5% Silymarin and 0.5% Carbopol.
4. Composition in accordance with claims 1 to 3 where the pharmaceutical composition may be in the form of an oral dose.
- 20 5. Composition in accordance with claim 4 where the oral form may be a suspension, oral solution, emulsion, gel, hard gelatin capsule, soft gelatin capsule, immediate release tablet, controlled release tablet, prolonged release or sustained release tablet.
- 25 6. Composition in accordance with claim 5 where it is preferably in the form of an oral suspension.
7. The use of the composition of claim 1 based on Silymarin and Carbopol for the manufacture of a medicine that is useful in the recovery of the functioning of
30 the pancreatic β cells.
8. The use in accordance with claim 7 where the functioning of the pancreatic β cells causes the production of insulin.

9. Procedure for obtaining the composition of claims 1 to 3 consisting of the following steps:

- a) Dissolution of 0.2 to 0.6% of Carbopol in deionized water, subjecting it to agitation for a period of time of 50 to 90 minutes.
- 5 b) Addition of Silymarin in a percentage of 3 to 7 to the foregoing dissolution and subjected to agitation for a minimum period of one hour until a homogenous mixture is obtained.

10. Procedure in accordance with claim 9 where preferably 0.5% of Carbopol and 5% of Silymarin are dissolved.

11. Process in accordance with claim 9 where it optionally has a subsequent step of solubilization.

15 12. Process in accordance with claim 9 where it optionally has a subsequent step of emulsification.

13. Process in accordance with claim 9 where it optionally has a subsequent step of gelation.

20 14. Process in accordance with claim 9 where it optionally has a subsequent step of encapsulation.

25 15. Process in accordance with claim 9 where it optionally has a subsequent tablet-making step.

16. The use in accordance with claims 7 and 8 where the administration dose is from 60 to 220 mg/Kg.

30 17. The use in accordance with claims 11 through 15 where the preferred dose is 200 mg/Kg.